lactose, dextrose, sorbitol, dextran, mannitol and mixtures thereof, the ratio of said active substance to said phospholipid surface modifier is from about 3:1 to about 5:1 and the amount of said phospholipid surface modifier is in the range from about 0.2% w/w to about 5.0% w/w, wherein said composition is devoid of surfactants that require during terminal steam sterilization elevation of their cloud point temperature by addition of a cloud point modifier, said composition is devoid of surfactant additives which coagulate on steam sterilization, and said volume weighted mean particle size is not increased more than two-fold during and after terminal steam sterilization, and the ratio of the amount of the active substance and the thermoprotecting agent selected to provide particle size stability during and after terminal steam sterlization.

E1 Cont

22. (Twice Amended) An autoclavable composition of an injectable non-flocculating aqueous terminally steam sterilized suspension under nitrogen in a sealed vial, said suspension containing particles of a water insoluble or poorly soluble drug substance with a volume weighted mean particle size of up to 3 μm with not more than 3000 particles of 10μm or greater size and not more than 300 particles of 25 μm or greater size, said particles surface stabilized with one or more phospholipid surface modifiers, and a pharmaceutically acceptable amount safe for parenteral administration of a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, the ratio of said drug substance to said surface modifier is about 3:1 to about 5:1, the amount of said surface modifier is in the range from about 0.2% w/w to about 5.0% w/w, and said volume weighted mean particle size is not increased more than two-fold during and after terminal steam sterilization, and wherein said composition is devoid of surfactants that require during terminal steam sterilization elevation of their cloud point temperature by addition of a cloud point modifier and devoid of surfactant additives which coagulate on steam sterilization, and the ratio of the amount of the active substance and the thermoprotecting agent selected to provide particle size stability during and after terminal steam sterlization.

E2

26. (Amended) The composition of claim 21 or claim 22, wherein the phospholipid surface modifier is selected from the group consisting of natural phospholipids and synthetic phospholipids.

E3

30. (Amended) The composition of claim 29, wherein the antifungal agent is itraconazole.

35. (Amended) The composition according to claim 22, wherein the water-insoluble or poorly water-soluble drug substance is suitable for either immediate release or sustained release delivery of said drug substance by parenteral administration.

38. (Amended) An aqueous suspension comprising particles of a water insoluble or poorly soluble biologically active substance, from about 0.2% w/w to about 5% w/w of one or more phospholipid surface modifiers, and a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, sealed in a vial under nitrogen atmosphere, said suspension containing particles of the water insoluble or poorly soluble biologically active substance with a volume weighted mean particle size of up to 3μm, with not more than 3000 particles of 10μm or greater size and not more than 300 particles of 25μm or greater size, wherein the ratio of the amount of the active substance to the phospholipid surface modifier and/or the thermoprotecting agent being selected so as to provide particle size stability during and after terminal steam sterilization, and the particle size subsequent to terminal steam sterilization is not more than about two-fold of the volume weighted mean particle size prior to the terminal steam sterilization, and the suspension is devoid of surfactants which coagulate on steam sterilization.

39. (Amended) An aqueous suspension comprising particles of a water insoluble or poorly soluble biologically active substance, from about 0.2% w/w to about 5% w/w of one or more phospholipid surface modifiers, and a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, sealed in a vial under nitrogen atmosphere, said suspension containing particles of the water insoluble or poorly soluble biologically active substance with a volume weighted mean particle size of up to 3μm, with not more than 3000 particles of 10μm or greater size and not more than 300 particles of 25μm or greater size, the ratio of the amount of the active substance to the phospholipid surface modifier and/or the thermoprotecting agent being selected to provide particle size stability during and after terminal steam sterilization wherein the particle size subsequent to terminal steam sterilization is not more than about two-fold of the volume weighted mean particle size prior to the terminal steam sterilization, wherein the suspension is substantially devoid of surfactants that require elevation of their cloud point temperature by addition of a cloud point modifier for further stabilization and the suspension is devoid of surfactants which coagulate on steam sterilization.

44. (Amended) The suspension of claim 38, wherein the one or more phospholipid surface modifiers are natural phospholipids or synthetic phospholipids.

E7 26 46. (Amended) The suspension of claim ~~38~~ 18, wherein the amount of the surface modifier provides a biologically active substance to surface modifier ratio of 3:1 to 5:1.

E8 27 48. (Amended) The suspension of claim ~~38~~ 18, wherein the composition also contains a pharmaceutical excipient for opthalmic, peroral, or transdermal administration of the water insoluble or poorly soluble bioligical active substance.

E9 34 56. (Amended) The suspension of claim ~~38~~ 18, wherein the water-insoluble or poorly water-soluble biologically active substance is at a pharmaceutically acceptable concentration for either immediate release or sustained release delivery of the active substance by parenteral administration.